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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/877,635	06/08/2001	James N. Herron	3278.2US	9774

24247 7590 02/09/2004

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EXAMINER	
LAM, ANN Y	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 02/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/877,635	HERRON ET AL.	
	Examiner	Art Unit	
	Ann Y. Lam	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-33,45 and 46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-33,45 and 46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 21-33 and 45-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21, lines 7-10, contains language that is confusing, and thus it is unclear what Applicant is claiming. For example, line 8 recites "which indicate binding..." It is unclear what indicates binding. Also, lines 8-9 recites "which indicate binding of the at least one indicator of coronary artery disease by a capture molecule..." It appears that "by a capture molecule" should be –with a capture molecule.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 21-33 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable Foster, 5,485,277, in view of Jackowski, 5,747,274.

Foster discloses the invention substantially as claimed. Foster discloses an assay system comprising: a waveguide (60) configured to generate an evanescent field over at least one planar surface having capture molecules for at least one indicator of coronary artery disease associated therewith; a light source (50) positioned to direct light into said waveguide; a light detector (350) for detecting fluorescent light passed through said planar surface and emitted as fluorescently labeled tracer molecule, which indicate binding of the at least one indicator of coronary artery disease by a capture molecule, are excited by the evanescent field (see column 11, line 65, column 14, lines 57-62, and column 15, lines 43-61 , said light detector generating an intensity signal indicating an intensity of said detected light; and a controller (i.e., processor, see column 8, lines 60-63) for monitoring said intensity signal and being capable of correlating said intensity signal to a concentration of at least one indicator of coronary artery disease in the sample.

As to claim 22, said waveguide is optically associated with a rear lens (see column 7, line 66 – column 8, line 2) oriented for reading light from said light source passing through said waveguide, to monitor coupling efficiency and beam quality.

As to claim 24, said at least one reaction area comprises a reservoir, see column 8, lines 56-59.

As to claim 25, said at least one reaction area comprises a well, see column 8, lines 56-59, and Figure 4(b).

As to claim 26, said controller (i.e., processor) is capable of correlating in a substantially continuous fashion, see column 8, lines 60-63, and column 9 line 29 – column 10, line 40.

As to claims 27 and 29, said controller is capable of being configured to effect said monitoring and said correlating until a reliable determination is made of whether said at least one indicator of coronary artery disease is present in an amount indicative of coronary artery disease, see column 8, lines 60-63, and column 9 line 29 – column 10, line 40.

As to claims 28 and 30, said controller is capable of being configured to output a signal that effects reporting of said reliable determination, see column 8, lines 60-63, and column 9 line 29 – column 10, line 40.

As to claim 31, said controller is capable of being configured to substantially simultaneously determine concentrations of a plurality of indicators of coronary artery disease, see column 8, lines 60-63, and column 9 line 29 – column 10, line 40.

As to claim 46, the system further comprises a first member (110) associated in liquid tight attachment with said at least one planar surface of said waveguide, wherein said first member, in conjunction with said waveguide, defines at least one reaction area for containing the biological liquid sample while said at least one planar surface of said waveguide defines a floor or ceiling of said at least one reaction area (see column 8, lines 56-59 and figure 4(b).)

However, Foster does not specifically disclose that the planar surface has capture molecules for at least one indicator of coronary artery disease.

As to claim 23, Foster does not disclose that the capture molecules include capture molecules that bind with at least a portion of at least one of a troponin, creatine kinase, or myoglobin molecule or complex.

As to claim 32, Foster does not disclose that said capture molecules comprise capture molecules that bind with at least a portion of at least one ischemic marker or at least one complex that includes at least one ischemic marker.

As to claim 33, Foster does not disclose that said capture molecules comprise capture molecules that bind with at least a portion of at least one marker released from cardiac tissue only after a myocardial infarction or at least one complex that includes marker released from cardiac tissue only after a myocardial infarction.

Foster does teach that the system is used for biochemical studies using immobilized molecules for binding to molecules in samples, see column 8, lines 56-63, and see column 11, line 35 – column 12, line 58, and teaches use of a fluorescence detector, see column 16, lines 51-56.

Jackowski likewise teaches an assay system comprising immobilized molecules, a waveguide, see column 27, line 47 – column 28, line 11, and column 29, lines 1-31, and fluorescence detector, see column 28, lines 12-38. In addition, Jackowski teaches use of capture molecules that bind with troponin, creatine kinase, or myoglobin, see column 4, lines 35-36, and column 5, lines 29-31, for the detection of myocardial infarction, see column 4, lines 32- column 8, line 31, and column 19, lines 8-14, and column 29, lines 51-63, and column 29, lines 51-63, and column 22, lines 1-12, wherein

the capture molecule is immobilized on a waveguide surface, see column 27, lines 38-58, and column 29, lines 1-27.

It would have been obvious to utilize the capture molecules for the detection of myocardial infarction, as taught by Jackowski, on the waveguide of Foster because Jackowski teach that the capture molecules can be used in various techniques available in optical sensor technology (see column 29, lines 28-31.)

2. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable Foster, 5,485,277, in view of Jackowski, 5,747,274, and further in view of Herron et al., 5,512,492.

Foster in view of Jackowski discloses the invention substantially as claimed (see above), except for the planar surface of the waveguide comprising optical plastic.

Foster does not disclose the specific material that is used to form the waveguide substrate.

However, Herron '492, like Foster, also discloses a waveguide having immobilized capture molecules on a surface and the use of evanescent-light immunofluorescence assay (see column 3, lines 12-18.) Herron further discloses that the waveguide may be formed from optical plastic as are well-known in the art (see column 6, lines 2-4.)

Since Foster and Herron both disclose evanescent-light immunofluorescence assay using a waveguide having immobilized capture molecules, and since Herron discloses that optical plastics are well known in the art as a material to form a

waveguide, it would have been obvious to one of ordinary skill in the art at the time the invention was made to form the Foster waveguide from optical plastic as is well known in the art.

Response to Arguments

Applicant's arguments filed November 3, 2003 have been fully considered but they are not persuasive.

Applicant argues that Foster lacks any teaching that the system includes a waveguide configured to generate an evanescent field, and that the metal film on the capture molecule-bearing surface of the waveguide would actually prevent the generation of an evanescent field at that surface.

In response, Examiner asserts that Foster discloses a waveguide configured to generate an evanescent field (see for example column 11, lines 63-67, column 14, lines 57-60.) The metal film does not prevent the generation of an evanescent field on the capture molecule-bearing surface of the waveguide (see column 11, lines 63-67.)

As to Applicant's argument on page 7 that Jackowski also fails to teach the waveguide of the present invention as claimed, Examiner asserts that the Jackowski reference is relied upon in the rejection for the teaching of the specific capture molecules used in the assay, as described in the above rejection, and that the waveguide as claimed is disclosed by Foster.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703)305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

A.L.

BAO-THUY L. NGUYEN
PRIMARY EXAMINER
2/6/04